

REMARKS

Claim 1-35 are pending. The Final Action, dated November 19, 2007, has been carefully considered. The above amendments and the following remarks are presented in a sincere attempt to place this Application in condition for allowance. Claims 1, 10, 16, 20 and 27 have been amended. Reconsideration and allowance are respectfully requested in light of the above amendments and following remarks.

Amendments to the Claims

Claims 1, 10, 16, 20 and 27 have been amended to clarify the invention. It is respectfully submitted that these amendments are only tangential to the invention. Support for these amendments can be found in the originally-filed application, for example, in paragraphs [0024], [0025], [0035]-[0036], [0038], [0067], [0087] and [0090]-[0095]. No new matter has been entered.

Rejection of Claim 24 Under 35 U.S.C. § 102

Claim 24 stands rejected under 35 U.S.C. § 102(b) as being assertedly anticipated by U.S. Patent No. 5,924,074 to Evans ("Evans"). Applicants respectfully traverse this rejection.

It is well settled that to anticipate a claim, a reference must teach every element of the claim. M.P.E.P. § 2131. Moreover, in order for a reference to be anticipatory under 35 U.S.C. § 102 with respect to a claim, "[t]he identical invention must be shown in as complete detail as is contained in the claim" and "[t]he elements must be arranged as required by the claim." M.P.E.P. § 2131, citing *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) and *In re Bond*, 15 US.P.Q.2d 1566 (Fed. Cir. 1990). Applicants respectfully assert that the rejection does not satisfy these requirements.

Independent Claim 24 recites “determining whether a patient file having a predetermined patient data structure exists for a patient on a remote system” It is respectfully pointed out that the cited passage of Evans does not disclose at least this limitation of Claim 24. Page 20 of the Final Action cites Figure 13 and column 8, lines 29-31 of Evans for “creation of a patient record” and a “patient data structure.” However, the cited passage of Evans does not disclose the first step of “determining whether a patient file having a predetermined patient data structure exists for a patient on a remote system” This step can avoid unintended overwriting of an existing patient record with new data or “blank” data record. This preparatory step is absent from Evans and would not be obvious in view of Evans. Therefore, Applicants assert that Evans does not teach every element of Claim 24 and that Claim 24 is patentable. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 102(b) rejection of Claim 24.

Rejections of Dependent Claims 25 and 26 Under 35 U.S.C. § 103 (a)

Claims 25 and 26 depend from base Claim 24 and thus inherit all the limitations of Claim 24. As shown above, Evans does not teach every limitation of Claim 24 and therefore, Claim 24 is patentable over Evans. Applicants assert that Claims 25 and 26 are patentable for, at least, their dependence from Claim 24. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 25 and 26.

Rejections Of Independent Claims 1, 10, 23, 27 and 29 Under 35 U.S.C. § 103(a)

Rejections Over Evans and Nichols

Independent Claims 1, 10, 23, 27 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans in view of U.S. Patent No. 7,039,810 to Nichols et al. (“Nichols”). Applicants respectfully traverse these rejections.

In order to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the prior art reference (or references when combined) must teach or suggest all the claim limitations. M.P.E.P. § 2143. Applicants respectfully assert that the rejections do not satisfy these criteria.

Independent Claim 1

Independent Claim 1 recites “a record encapsulation system configured to encapsulate a medical record data file, wherein encapsulation enables detection of modification to the medical record data file and a record server configured to encrypt the encapsulated medical record data file” Evans is not relied upon for this aspect of Claim 1, and the cited passages of Nichols do not teach, suggest or disclose at least this aspect of Claim 1. Pages 2-3 of the Final Action cite Figure 5 along with col. 2, lines 54-56 and col. 15, lines 9-15 of Nichols in the rejection of Claim 1.

Applicants respectfully point out that the cited passages of Nichols do not teach, suggest or disclose a record encapsulation system and a record server configured to encrypt the encapsulated medical record data file, as required by Claim 1. Instead, Nichols teaches only encryption without encapsulation. Nichols, col. 2, lines 54-67 and col. 15, lines 9-15 and 47-49.

“Encapsulation” of a medical record that “enables detection of modification to the medical record data file” is different from mere “encryption” of a medical record. “Encryption” prevents access to a medical file by an *unauthorized* user who does not know the appropriate password. “Encapsulation,” by contrast, “enables detection of modification to the medical record data file” by even users who have access to the file with the appropriate passwords. See, Specification, pages 9, par. 24 and pages 31-33, pars. 83-87. “Encryption” alone (as taught by Nichols) does not accomplish this because authorized users would remain free to modify the medical records after they are de-crypted by use of the correct password.

For example, suppose that an encrypted medical record (as in the Nichols/Evans combination proposed by the Examiner) erroneously contained in an incorrect x-ray (for, example, an x-ray for another person). In a Nichols/Evans system, an *authorized* person, after accessing the file by de-crypting, may notice that the x-ray is incorrect, substitute the correct x-ray, and then close the file (re-encrypting it). Such an authorized person may do so either innocently (only intending to make the file correct), or with intent to conceal the fact that the file previously included an incorrect x-ray. In the Nichols/Evans combination proposed by the Examiner, if the medical file is later reviewed, it would include the correct x-ray, not the prior, incorrect one. Furthermore, if the person accessing the file was not acting innocently and intended to conceal the prior error, and changed the computer clock date and time prior to performing the substitution, it could appear that the correct x-ray was placed in the file at an earlier time than it was. Thus, the “encryption” combination of Nichols with Evans, as suggested by the Examiner, would neither detect nor prevent this modification of the file; instead, there would be no record the prior, incorrect x-ray was ever in the file, or what that incorrect x-ray showed.

The present invention as defined in Claim 1, as amended, solves this problem. In particular, the “encapsulation” “enables detection of modification to the medical record data file” (by even *authorized* users with the appropriate passwords). Furthermore, because Claim 1 also provides “in case of modification, causes automatic preservation of the version of the medical record data file prior to modification,” the modified file would not only include the correct x-ray, the file would also automatically preserve the version of the medical record as it previously existed, prior to modification. This will ensure that the entire history of the medical file (including prior errors as well as the correction of those errors) is permanently preserved. These features, and the advantages

accruing from them are neither taught nor suggested by the hypothetical combination of Evans and Nichols suggested by the Examiner.

Therefore, Applicants assert that the proffered combination of Evans and Nichols does not teach, suggest or disclose all the limitations of Claim 1. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 1.

Independent Claim 10

Similar to Claim 1, independent Claim 10 recites “encapsulating medical record data” and also has been amended to recite “wherein encapsulation enables detection of modification to the medical record data file and, in case of modification, causes automatic preservation of the version of the medical record data file prior to modification.”

As with Claim 1, Applicants respectfully submit that the cited passages of Nichols do not teach, suggest or disclose a record encapsulation system and a record server configured to encrypt the encapsulated medical record data file, as required by Claim 10. Instead, Nichols teaches only encryption without encapsulation. Nichols, Fig. 5, col. 2, lines 54-67 and col. 15, lines 9-15 and lines 47-49. As previously discussed, “encapsulation,” by contrast, “enables detection of modification to the medical record data file” (by even users with appropriate access to the file). “Encryption” alone (as taught by Nichols) does not accomplish this because authorized users would remain free to modify the medical records after they are de-crypted by use of the correct password.

Furthermore, because Claim 10, like Claim 1, also provides “in case of modification, causes automatic preservation of the version of the medical record data file prior to modification,” the modified file would not only include the correct x-ray, the file would also automatically preserve the version of the medical record as it previously existed, prior to modification. This will ensure that the entire history of the medical file (including prior errors as well as the correction of those errors)

is permanently preserved. These features, and the advantages accruing from them are neither taught nor suggested by the hypothetical combination of Evans and Nichols suggested by the Examiner.

Therefore, Applicants assert that the proffered combination of Evans and Nichols does not teach, suggest or disclose all the limitations of Claim 10. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 10.

Independent Claim 23

Independent Claim 23 recites “a record server having an encapsulated medical record data file” with “medical record data that can be viewed but which cannot be modified.” The cited passages of Nichols do not teach, suggest or disclose at least these aspects of Claim 23. Pages 8-9 of the Final Action cites Figure 5 along with col. 2, lines 54-56 of Nichols in the rejection of Claim 23. However, the cited passages of Nichols do not teach, suggest or disclose a record server having an encapsulated data that cannot be modified, as required by Claim 23. As established above for Claims 1 and 10, the cited portion of Nichols teaches merely encryption. Such encryption (as taught by Nichols) prevents a file from being accessed by an unauthorized user, but does nothing to prevent modification of the file after de-cryption for viewing by a user having authorized access to the file, as does the present invention defined by Claim 23.

Therefore, Applicants assert that the proffered combination of Evans and Nichols does not teach, suggest or disclose all the limitations of Claim 23. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 23.

Independent Claim 27

Independent Claim 27 recites “receiving encapsulated comment data associated with the excerpt” and, as presently amended, also recites, similarly to Claims 1 and 10, “the encapsulated

comment data enabling detection of modification to the comment data and, in case of modification, causes automatic preservation of the version of the comment data file prior to modification.”

The cited passage of Evans does not disclose at least this limitation of Claim 27. Page 9 of the Final Action cites Figure 4, col. 3, lines 36-42, col. 4, line 54 to col. 5, line 8 and col. 6, lines 31-36 of Evans. However, the cited passage of Evans does not disclose receiving encapsulated comment data associated with an excerpt, as the Examiner acknowledges. The Examiner contends, however, that Nichols discloses encryption of such data. However, as discussed above with respect to Claim 1 and 10, “encryption,” as taught by Nichols, is not the same as “encapsulation,” as required by Claim 27. Furthermore, nowhere does Nichols disclose or suggest “the encapsulated comment data enabling detection of modification to the comment data and, in case of modification, causes automatic preservation of the version of the comment data file prior to modification,” as also required by Claim 27, as currently amended.

Therefore, Applicants assert that the hypothetical combination of Evans proposed by the Examiner neither discloses nor suggests the invention defined by Claim 27. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 27.

Independent Claim 29

Independent Claim 29 recites “encapsulating an electronic medical record file to allow viewing and to prevent modification of medical record.” The Examiner relies upon Evans for various asserted disclosures, but acknowledges that Evans does not teach the claimed encapsulating of an electronic medical record to prevent modification of the medical record file, the claimed encryption of the file or the claimed transmitting of the encrypted encapsulated file.

Page 4 of the Final Action cites Figure 5 along with col. 15, lines 9-15 of Nichols in the rejection of Claim 29, to assertedly supply the missing teachings. However, the cited portions of

Nichols do not teach, suggest or disclose at least these aspects of Claim 29, because the cited passages of Nichols do not teach, suggest or disclose a record server having an encapsulated data that can be viewed but cannot be modified, as required by Claim 29. Such encryption (as taught by Nichols) prevents a file from being accessed for viewing by an unauthorized user, but does nothing to prevent modification of the file after de-cryption for viewing, as does the present invention defined by Claim 29.

Therefore, Applicants assert that the proffered combination of Evans and Nichols does not teach, suggest or disclose all the limitations of Claim 29. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 29.

Rejections Over Evans and Portwood

Independent Claim 16

The independent Claim 16 has now been clarified to recite that the “medical supplies” are “packaged medical supplies,” in addition to the prior recital requiring “a record server configured to transmit medical supply package data to a record client and to correlate the package data with verification data received from the record client.” It is respectfully pointed out that the cited passages of Evans and Portwood do not teach or suggest at least these aspects of Claim 16. Page 13 of the Final Action cites column 14, lines 8-16 of Evans and the abstract, column 3, lines 43-49 and column 7, lines 35-37 of Portwood. However, the cited passages do not teach, suggest or disclose a record server configured to transmit medical supply “package” data to a record client and to correlate the package data with verification data received from the record client, as required by Claim 16.

The cited portion of Evans discloses merely a database connection among computers. The cited portions of Portwood disclose that “prescription information for the patient” is “transferred to the server.” It is respectfully submitted that this information is not “package” data, as required by the Claim. See Portwood, col. 7, lines 35-37 in light of col. 7, lines 16-17. To the contrary, Portwood makes it clear that this is merely “pharmaceutical” information about the drugs being prescribed so that it can be compared to patient data and checked for appropriateness of the drug for that patient, such as underdosing, overdosing, length of therapy, drug-drug interactions, drug-food interactions, drug-alcohol interactions, and prior adverse reactions.

Applicants’ invention as defined in Claim 16, by contrast, concerns ensuring the integrity of an entirely different aspect of medical safety – verifying that the data relating to the actual packaged medical supplies (i.e., after the prescription has been “filled” and the drugs or medical supplies are packaged for delivery to the patient or other recipient) match the information relating to the prescription that was written for the patient. By contrast, Portwood is concerned only with ensuring that the right amount and right kind of drugs are prescribed in the first place; for example that a prescription for a one month supply of once-a-week 70 mg pills of Fosamax ® is appropriate for a 70 year old, 140 pound female with osteoporosis. However, Portwood, even combined with Evans, teaches nothing that ensures that the patient actually receives the intended Fosamax ®, rather than some other drug that may have a similar-looking package. That mistake can easily happen and have disastrous consequences. The present invention solves that problem – Evans and Portwood do not. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 16.

Rejection of Independent Claim 20 Over Portwood and Evans

Independent Claim 20 has now been clarified to recite “storing package data corresponding to a sealed package of medical supplies”; and “physically transporting the sealed package to a remote site,” along with the limitations of “receiving the package data from the remote site; and authorizing release of the package if the stored package data matches the received package data” previously presented. (Emphasis added). Applicants respectfully assert that the cited passages of Portwood and Evans do not teach, suggest or disclose all these limitations of Claim 20.

Page 16 of the Final Action asserts Portwood, at col. 2, lines 60-66, teaches storing package data corresponding to a sealed package of medical supplies. This assertion is respectfully traversed. However, in fact, the cited portion of Portwood merely recites “a data storage unit containing stored pharmaceutical data, a central processing unit (CPU) programmed and operatively connected to the data storage unit to further store in the data storage unit patient data and patient prescription data.” There is nothing in this that discloses or suggests that this data corresponds to a “sealed package of medical supplies,” as required by Claim 20.

Page 16 of the Final Action further asserts that Portwood, at col. 5, lines 7-10, discloses transmitting the sealed package to a remote site. However, in fact, the cited portion of Portwood merely recites that “prescription distribution system D [] enables quicker initial delivery and which better ensures timely refills of prescriptions.” However, reference to block “D” of Fig. 1 of Portwood, in conjunction with col. 18, lines 36-46, shows that all that is being “transmitted” is information about the prescription; there is nothing disclosed or suggested about “physically transporting” a “sealed package of medical supplies,” to a “remote site,” as specifically required by Claim 20.

Page 16 of the Final Action further asserts that Portwood, at col. 3, lines 36-41, discloses authorizing release of the package if the stored package data matches the received package data. However, in fact, the cited portion merely recites that “the CPU is further programmed to generate a prescription delivery message.” There is nothing disclosed or suggested in Portwood about “authorizing release of the package if the stored package data matches the received package data,” as required by Claim 20.

Page 16 of the Final Action further asserts that col. 2, lines 45-47 and column 10, lines 18-23 of Evans as allegedly teaching a system for instant access to a patient’s electronic medical record. However, the cited passages of Evans teach accessing a particular patient’s comprehensive medical record, whereas Claim 20 requires receiving package data corresponding to a sealed package of medical supplies which is *physically transported* to a remote site.

It is respectfully pointed out that the cited passages of Evans and Portwood do not teach or suggest the invention defined by Claim 20. The cited portion of Evans discloses merely a database connection among computers. The cited portions of Portwood disclose transmission of data about a prescription, but have nothing to do with physically transporting a sealed package of medical supplies and ensuring that the correct sealed package arrives at the remote destination.

Applicants’ invention as defined in Claim 20 concerns ensuring the integrity of an entirely different aspect of medical safety that Evans or Portwood – verifying that the sealed package of medical supplies that was physically transported to a remote site is, in fact, the same sealed package of medical supplies that is received at the remote site. Certain prescription drugs, such as controlled substances like Oxycotin ®, are frequently stolen by persons in the drug distribution chain. To attempt to conceal a theft, a thief may switch a package of another drug for the controlled substance drug being stolen. Thus, a patient prescribed Oxycotin ® for a legitimate purpose may have their

prescription label peeled off and placed on a package of Fosamax ®, for example (the thief keeping the Oxycotin ®). The present invention as defined in Claim 20, however, by also “authorizing release of the package if the stored package data matches the received package data,” in conjunction with the other recited limitations, ensures that this will not happen. Evans and Portwood are not addressed to and do not solve this problem. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 20.

Dependent Claims 17, 19, 21-22, 25-26, 32 and 34-35

Dependent Claims 17, 19 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans in view of U.S. Patent No. 6,305,377 to Portwood et al. (“Portwood”). Dependent Claim 18 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans in view of Portwood and in further view of Nichols. Dependent Claims 21-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Portwood in view of Evans. Dependent Claims 25, 26 and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans. Dependent Claim 34 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans in view of Portwood and in further view of U.S. Patent No. 6,370,841 to Chudy et al. (“Chudy”).

Dependent Claim 32

Claim 32 depends from base Claim 1 and thus inherits all the limitations of Claim 1. Page 3 of the Final Action admits that Evans does not teach all the limitations of Claim 1, and therefore Claim 1 is not rejected over Evans alone. The Final Action attempts to address the deficiencies of Evans with respect to the rejection of Claim 1 by introducing Nichols. However, Nichols is not relied upon for the rejection of Claim 32. Therefore, Applicants assert that the 35 U.S.C. § 103(a) rejection of Claim 32 is improper and request withdrawal of the rejection.

Dependent Claims 17, 19 and 35

Claims 17, 19 and 35 depend from base Claim 16 and thus inherit all the limitations of Claim 16. As shown above, the proffered combination of Evans and Portwood does not teach, suggest or disclose all the limitations of Claim 16. Therefore, the proffered combination of Evans and Portwood does not teach, suggest or disclose all the limitations of Claims 17, 19 and 35. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 17, 19 and 35.

Dependent Claim 34

Claim 34 depends from base Claim 16 and thus inherits all the limitations of Claim 16. As shown above, the proffered combination of Evans and Portwood does not teach, suggest or disclose all the limitations of Claim 16. Chudy is not relied upon to cure the deficiencies of Evans and Portwood. Therefore, the proffered combination of Evans, Portwood and Chudy does not teach, suggest or disclose all the limitations of Claim 34. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 34.

Dependent Claim 18

Claim 18 depends from base Claim 16 and thus inherits all the limitations of Claim 16. As shown above, the proffered combination of Evans and Portwood does not teach, suggest or disclose all the limitations of Claim 16. Nichols is not relied upon to cure the deficiencies of Evans and Portwood. Therefore, the proffered combination of Evans, Portwood and Nichols does not teach, suggest or disclose all the limitations of Claim 18. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 18.

Dependent Claims 21 and 22

Claims 21 and 22 depend from base Claim 20 and thus inherit all the limitations of Claim 20. As shown above, the proffered combination of Portwood and Evans does not teach, suggest or disclose all the limitations of Claim 20. Therefore, the proffered combination of Portwood and Evans does not teach, suggest or disclose all the limitations of Claims 21 and 22. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 21 and 22.

Dependent Claims 2-9, 11-15, 30, 31 and 33

Claims 2-9, 11-15, 30, 31 and 33 depend from a respective one of independent Claims 1, 10 and 29 and thus inherit all the limitations of their respective independent claim. As shown above, the proffered combination of Evans and Nichols does not teach, suggest or disclose all the limitations of Claims 1, 10 or 29. Therefore, the proffered combination of Evans and Nichols does not teach, suggest or disclose all the limitations of Claims 2-9, 11-15, 30, 31 and 33. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejections of Claims 2-9, 11-15, 30, 31 and 33.

Dependent Claim 28

Claim 28 depends from independent Claim 27 and thus inherits all the limitations of Claim 27. As shown above, Evans does not teach every limitation of Claim 27 and therefore, Claim 27 is patentable over Evans. Applicants assert that Claim 28 is patentable for, at least, its dependence from Claim 27. Accordingly, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 28.

Conclusion

Applicants have made an earnest attempt to place this Application in condition for allowance. For the foregoing reasons and for other reasons clearly apparent, Applicants respectfully request full allowance of Claims 1-35. Should the Examiner deem that any further amendment is desirable to place this application in condition for allowance, the Examiner is invited to telephone the undersigned at the number listed below.

Please charge the fee of \$230.00 for a two months extension of time to Deposit Account No. 50-0605 of CARR LLP. In the event that any additional fees are due, the Commissioner is hereby authorized to charge any required fees due (other than issue fees), and to credit any overpayment made, in connection with the filing of this paper to Deposit Account No. 50-0605 of CARR LLP.

Respectfully submitted,

CARR LLP

Dated: April 21, 2008
CARR LLP
670 Founders Square
900 Jackson Street
Dallas, Texas 75202
Telephone: (214) 760-3032
Fax: (214) 760-3003

/Theodore F. Shiells/
Theodore F. Shiells
Reg. No. 31,569